

REMARKS**Claim Amendments**

After entry of this amendment, claims 17-53 will be pending in this application.

Claims 17, 26, 29, 35 and 47 have been amended. Support for the amendments to claims 17 and 35 can be found in previously submitted claims 26 and 47 and in paragraphs 96 and 108 of US2004/0171826 (the publication of the present patent application). Claims 26 and 47 have been amended to cancel certain subject matter. Claim 29 has been amended to correct a minor typographical error noted by the Examiner. None of the claim amendments adds new matter.

Claims 52 and 53 have been added. Support for these claims can be found in paragraph 124 of US2004/0171826 (the publication of the present patent application). These claims do not add any new matter.

In the Office Action, the Examiner states that claims 1-48 are pending in this application. Applicant respectfully notes that claims 49-51 were also pending at the time that the Office Action was issued. These claims were introduced in the Amendment submitted with Applicant's Amendment and Response to Office Communication, filed October 6, 2005. Accordingly, Applicant requests consideration of these claims.

Rejection under 35 U.S.C. 112, first paragraph

Claims 17-48 stand rejected as failing to comply with the written description requirement. The Examiner states that the claims read on a genus of recombinant nucleic acids encoding any endomannosidase activity that is targeted to any vesicular compartment within the host cell (Office Action, p. 3). According to the Examiner, the claims read "on expression or any variant, mutant, allele, derivative or homolog of an endomannosidase protein from any species or source or a fusion protein comprising a portion comprising a protein (or peptide) having endomannosidase activity" (*id.* at p. 4). The Examiner states that "[t]he prior art discloses a single species (a rat endomannosidase nucleic acid and protein sequence) and applicant discloses putative human, mouse and another rat

endomannosidase" (*id.* at p. 3). The Examiner states that the specification satisfied the written description requirement for these specific, disclosed, endomannosidase-encoding sequences (*id.*).

The Examiner acknowledges that the written description requirement for a genus may be satisfied by sufficient description of a representative number of species by disclosure of the relevant identifying characteristics of the genus, or by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed invention (Office Action, pp. 3-4). However, the Examiner states that "applicant has not presented a structure function relationship correlating the structure of the endomannosidases and their function" (*id.*).

Applicant traverses the Examiner's rejection to the extent that the rejection is applicable to the amended claims. The claims have been amended herein to recite the use of a nucleic acid encoding a polypeptide having endomannosidase activity, wherein said nucleic acid is selected from the group consisting of: (a) a nucleic acid that hybridizes under stringent conditions to SEQ ID NO:1 or SEQ ID NO:3; and (b) a nucleic acid that encodes a polypeptide that is at least 75% identical to the polypeptide of SEQ ID NO:2 or SEQ ID NO:4. Thus, the claims as amended do not read on the use of a nucleic acid encoding *any* protein having an endomannosidase activity. Further, as discussed in more detail below, Applicant has demonstrated a structure/function correlation with respect to nucleic acids encoding an endomannosidase activity.

The amended claims recite both a structural limitation ("a nucleic acid that hybridizes under stringent conditions to SEQ ID NO:1 or SEQ ID NO:3" or "a nucleic acid that encodes a polypeptide that is at least 75% identical to SEQ ID NO:2 or SEQ ID NO:4") and a functional limitation. The specification provides at least three examples of nucleic acids having the claimed structural and functional limitations: (1) the nucleic acid of SEQ ID NO: 1 encoding a human endomannosidase; (2) the nucleic acid of SEQ ID NO: 3 encoding a mouse endomannosidase; and (3) the nucleic acid encoding a rat endomannosidase (corresponding GenBank Accession No. AF023657). As disclosed in the specification, SEQ ID NO:1 is 77.8% identical to the nucleic acid encoding the rat

endomannosidase), and SEQ ID NO:3 is 86% identical to the nucleic acid encoding rat endomannosidase. (See paragraphs 92 and 104 of US2004/0171826.) The fact that the specification discloses three species which meet the structural and functional limitations recited in the claims demonstrates that there is a structure/function correlation and provides ample support for the amended claim language.

The United States Patent and Trademark Office has issued Written Description Guidelines for the Examination of Patent Applications (see MPEP 2163). Applicant directs the Examiner's attention to Example 9 of the "Revised Interim Written Description Guidelines Training Materials" obtained from the USPTO website. In Example 9 of the Guidelines, the specification discloses a single cDNA (SEQ ID NO:1) which encodes a protein having a specified biological activity. The claim is directed to a genus of nucleic acids, all of which must hybridize to SEQ ID NO: 1 under stringent hybridization conditions, and must encode a protein with a specific activity. The Guidelines conclude that the claim is adequately described. The Guidelines state:

A person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of the DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention.

Based on the analysis presented in the Guidelines, Applicant respectfully submits that the claims of the instant application are adequately described. As in Example 9 of the Guidelines, the claims of the instant application use both *structure and function* to define the endomannosidases to be used in the claimed methods. Further, the instant specification discloses *three* species that fall within the recited genus, rather than a single species as disclosed in Example 9 of the Guidelines. Based on the structural and functional limitations recited in the amended claims and based on the information disclosed in the specification regarding three different species of endomannosidases that have the structural and functional characteristics recited in the claims, a person of skill in the art would not expect substantial variation among the species encompassed within the claims and would recognize

that the Applicant was in possession of the claimed invention at the time the application was filed.

In view of the claim amendments and the arguments presented above, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

Conclusion

Entry of this Amendment and allowance of the claims as submitted herewith is respectfully requested.

Applicant believes no fee, other than the fee for the accompanying petition for a one month extension of time, is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-1075, under order no. 001634-0012, from which the undersigned is authorized to draw.

Respectfully submitted,



Barbara A. Ruskin (Reg. No. 39,350)
Gloria Fuentes (Reg. No. 47,580)

Attorneys for Applicant

FISH & NEAVE IP GROUP
ROPES & GRAY LLP
Customer No. 1473
1251 Avenue of the Americas
New York, New York 10020-1104
Tel.: (212) 596-9000
Fax: (212) 596-9090